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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,576	HOCHRAINER ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7, 9-10, 12-14, 17-21, 25-34 (renumbered 35-44)* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7, 9-10, 12-14, 17-21, 25-34 (renumbered 35-44)* is/are rejected.

7)☒ Claim(s) *1,7, 9-10, 12-14, 17-21, 25-34 (renumbered 35-44)* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the Notice of Withdrawal from Issue mailed March 4, 2008. As indicated in the Notice of Withdrawal from Issue the application was withdrawn to permit reopening of prosecution due to unpatentability of one or more claims.

2. According to the Notice of Allowability, mailed October 17, 2007, claims 1, 7, 9, 10, 12-14, 17-21, and 25-34 were allowed.

The Examiner's Amendment, mailed October 17, 2007 states that authorization was given in a telephone interview with Mr. Mathew Denier on 10/5/07 to amend page 4 of the amendment dated 8/31/07, to change cancelled "claims 22-34" to "22-24." However, once a claim is cancelled, it is cancelled. Any new claims must be presented with a new consecutive number. See: MPEP 714(c).

In the instant case, claims 22-34 were originally cancelled on page 5 of the amendment filed 6/28/06. Claims 22-34 were indicated as being cancelled in the amendment filed 12/11/06, in the amendment filed 8/28/07, and in the amendment filed 8/31/08. However, in the amendment filed 8/28/07 applicant reintroduced claims 25-33 and in the amendment filed 8/31/07 applicant reintroduced claim 34.

It appears applicant intended to number currently numbered claims 25-34 as claims 35-44 and they will be examined accordingly. However, appropriate correction is required.

Thus, claims 1, 7, 9-10, 12-14, 17-21 and 25-34 (renumbered as 35-44) are pending in this application.

Allowable Subject Matter is Hereby Withdrawn

3. The indicated allowability of claims 1, 7, 9, 10, 12-14, 17-21, and 25-34 (renumbered as claims 35-44) is withdrawn for the reasons set forth below.

Claim Objections

4. Claims 1, 7, 9-10, 12-14, 17-21 and 25-34 (renumbered as claims 35-44) are objected to because of the following informalities:

In the claims, when the term "the" or "said" is used, the word following the term "the" or "said" must have proper antecedent basis. The terms "the" and "said" appear numerous times in the claims without proper antecedent basis for the limitations following the terms "the" and "said."

For example, Claim 1 recites the limitation "the device for supplying the powder formulation" in line 7; however, there is insufficient antecedent basis for this limitation in the claim and it is unclear if applicant is referring to the dry powder inhaler, the multidose blister, or, a completely different device.

Claim 1 recites the limitation "the powder particles" in line 10; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to particles from the powder formulation or different powder particles.

Claim 1 recites the limitation "the inhaler" in line 12; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to the "dry powder inhaler" or a different inhaler as applicant has only provided antecedent basis for "the dry powder inhaler" and they are reminded to be consistent in their terminology.

In line 1 of claims 7, 9-10, 12-14, and 17-21 it is unclear if applicant is referring to "The dry powder inhaler" of claim 1 or a different "Dry powder inhaler." The examiner respectfully suggests placing the word "The" prior to "Dry powder inhaler" if they intend to refer back to the same dry powder inhaler as claimed in claim 1.

In claim 9, applicant lacks antecedent basis for the term "the pressure medium" as they have only provided antecedent basis for "the gaseous pressure medium" and it is unclear if they are referring back to "the gaseous pressure medium" or a different "pressure medium." Claims 12-13 are objected to for analogous reasons.

Claim 12 is also objected to for its use of the terms "N2" and "CO2" as these chemical compounds are correctly written with the numerals in subscript (i.e. "N_2" and CO_2).

Claims 13 & 14 are objected to for the use of the term "the device" as it is unclear if it is referring to "the device for supplying the powder formulation" or a completely different device.

Claims 19-21, 36-77, and 39 are objected to as lacking antecedent basis for the term "the aerosol flow."

Claim 35 recites the limitation "the device for supplying the powder formulation" in line 7; however, there is insufficient antecedent basis for this limitation in the claim and it is unclear if applicant is referring to the dry powder inhaler, the multidose blister, or, a completely different device.

Claim 35 recites the limitation "the powder particles" in line 10; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to particles from the powder formulation or different powder particles.

Claim 35 recites the limitation "the inhaler" in line 12; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to the "dry powder inhaler" or a different inhaler as applicant has only provided antecedent basis for "the dry powder inhaler" and they are reminded to be consistent in their terminology.

Claim 37 is objected to as lacking antecedent basis for the terms "the inlet channels" and "the inhalation air."

Claim 38 recites the limitation "the device for supplying the powder formulation" in line 7; however, there is insufficient antecedent basis for this limitation in the claim and it is unclear if applicant is referring to the dry powder inhaler, the multidose blister, or, a completely different device.

Claim 38 recites the limitation "the powder particles" in line 12; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to particles from the powder formulation or different powder particles.

Claim 38 recites the limitation "the inhaler" in lines 13-14; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to the "dry powder inhaler" or a different inhaler as applicant has only provided antecedent basis for "the dry powder inhaler" and they are reminded to be consistent in their terminology.

Claim 40 is objected to as lacking antecedent basis for the terms "the inlet channels" and "the inhalation air."

Claim 41 recites the limitation "the powder particles" in line 10; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to particles from the powder formulation or different powder particles.

Claim 42 is objected o for lacking antecedent basis for "the narrowest cross section" and it is unclear if they are referring back to the "section of narrowest cross-section" in claim 41 or a different "narrowest cross section." Applicant is reminded to be consistent in their terminology.

Claim 43 recites the limitation "the powder particles" in line 9; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to particles from the powder formulation or different powder particles. Claim 43 is also objected to because it lacks antecedent basis for "the flow" and it is unclear which flow applicant is referring to.

Claim 44 is objected to because it refers to the "the powder particle" not "the powder particles."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 7 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., (6,089,228).**

Smith discloses a dry powder inhaler with a mouthpiece (32) for dispensing pharmaceutical drug formulations, a Laval nozzle (also known as a convergent-divergent nozzle as shown in figure 12B) communicating with the mouthpiece (at 114 where the nozzle narrows in Fig. 12B), a multidose blister container for supplying a powder formulation (see: 12 of figure 1) in communication with the Laval nozzle, an auxiliary energy source in the form of a pressure medium system (338, 390) in communication with the device for supplying the powder formulation, upon activation of the pressure medium system a gaseous pressure medium is released into the device for supplying the powder formulation and forms an aerosol with the powder formulation in such a way that the powder particles are present in dispersed form within the gaseous pressure medium prior to entering the Laval nozzle entering the mouthpiece and leaving the inhaler.

With respect to claim 7, Smith discloses a narrowest cross section of the Laval nozzle is about 100 um to 1500 um (Col. 14, lines 59-67).

Regarding claim 35, Smith discloses a dry powder inhaler with a mouthpiece (32) for dispensing pharmaceutical drug formulations, a nozzle (convergent-divergent nozzle as shown in figure 12B) communicating with the mouthpiece (at 114 where the nozzle narrows in Fig. 12B), a multidose blister container for supplying a powder formulation (see: 12 of figure 1) in communication with the nozzle, an auxiliary energy source in the form of a pressure medium system (338, 390) in communication with the device for

supplying the powder formulation, upon activation of the pressure medium system a gaseous pressure medium is released into the device for supplying the powder formulation and forms an aerosol with the powder formulation in such a way that the powder particles are present in dispersed form within the gaseous pressure medium prior to entering the nozzle entering the mouthpiece and leaving the inhaler.

7. **Claims 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ingle et al (2001/0029948).**

In fig. 3, Ingle teaches an inhaler comprising a mouthpiece (54), an aperture (44), a device for supplying powder formulation (40), and an auxiliary energy source (48). Upon activation of the pressure medium system (energy source 48) gaseous pressure medium is released for supplying the powder formulation, and forms an aerosol with the powder formulation in such a way that the powder particles are present in dispersed form within the gaseous pressure medium, forming a particle laden gas prior to entering the aperture (see paragraph 34). Aperture 44 will inherently introduce turbulence to the flow of particle laden gas to some degree. Moreover, Ingle states that the "high shear rate inside the extraction tube (aperture) further deagglomerates the powder" (see: paragraph 36). Clearly the "high shear rate" will introduce some degree of turbulence.

Regarding claim 44, Ingle discloses powdered having a mean size from about 0.5um to about 10 um, which overlaps the 1-5 um powder particle size claimed. See: paragraph [0025].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 9, 12-13, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., (6,089,228) as applied to claim 1 above and further in view of Taplin et. al. (2,693,805).**

Smith discloses a dry powder inhaler with all the limitations of claim 9, except the pressure medium system including a pump that uses ambient air as the pressure medium.

Taplin teaches a dry powder inhaler with pressure medium system that includes a pump (17) that uses ambient air as the pressure medium.

It would have been obvious to one having ordinary skill in the art a the time the invention was made to have modified the pressure medium system disclosed by Smith by utilizing a pump pressure medium system as taught by Taplin that uses ambient air as the pressure medium in order to provide a pump that has a continually renewable gas for delivery system.

Regarding the specific gasses claimed in claim 12, the earths atmosphere contains approximately (by molar content/volume) 78.08% nitrogen, 20.95% oxygen, 0.93% argon, 0.038% carbon dioxide, trace amounts of other gases, and a variable

amount (average around 1%) of water vapor. Thus, it is reasonable to expect that ambient air inherently meets the claimed limitation.

With respect to claim 13, Taplin teaches a device for supplying the powder formulation that is placed between the pressure medium system and the Laval nozzle (at 21) in such a way that the pressure medium must pass through the device (Figs. 1-4).

With respect to claim 18, Taplin discloses an inlet channel (24), whereby inhalation air is drawn in through the inlet channel and whereby a swirling flow of the inhalation air is created between the outlet section and the inlet channel of the mouthpiece (Fig. 2) wherein the mouthpiece is considered to be the end portion (23).

With respect to claim 20, Taplin discloses that the Laval nozzle and an inlet channel (24) for inhalation air are arranged in such a way that the aerosol flow leaving the Laval nozzle and the inhalation air collide with each other at an angle (Fig. 2).

10. **Claims 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (6,089,228) and further in view of Lockhart et. al. (6,443,152).**

Smith discloses all the limitations of claim 10, except it lacks the explicit teaching of a pressure medium system that includes a cartridge that stores the pressure medium. However, at col. 13, lines 49-55, it teaches the "Gas source 20 may be in the form of a manual pump, an electric pump, a high pressure gas cylinder, or the like."

Lockhart teaches an inhaler device with a pressure medium system that includes a cartridge that stores the pressure medium (54, based upon standard dictionary

definition of a cartridge, "A small modular unit of equipment designed to be inserted into a larger piece of equipment" inasmuch as 54 is inserted into 52, element 54 is readable upon a cartridge).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the gas source or pressure medium system disclosed by Smith, with a cartridge as the pressure medium system, as taught by Lockhart, because the reasonable expectation that one gas delivery source could be replaced for another as suggested by Smith.

With respect to claim 13, Lockhart discloses that the device for supplying the powder formulation (20) is placed between the pressure medium system (52) and the Laval nozzle (48) in such a way that the pressure medium must pass through the device.

With respect to claim 14, Lockhart discloses that the device for supplying the powder formulation (20) comprises a capsule filled with powder.

11. **Claims 17 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (6,089,228), as applied to claim 1 above.**

Smith discloses all the limitations of claim 17 and 38 except the mouthpiece comprising a flow rate sensor that generates an input signal for the pressure medium system. However, breath actuated inhaler are well known in the art and Smith teaches that the release of the high pressure gas can be effected by a manual trigger or optionally by sensing negative pressure resulting from the patient's inspiration (i.e., can be breath-activated). See: col. 4, lines 52-55.

Thus, it would have been obvious to one having ordinary skill in the art to have added breath actuation to the inhaler disclosed by Smith because Smith suggests such a limitation in the specification and breath actuated inhalers are commonly known in the art.

12. **Claims 18, 21, 36, 37, 39, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (6,089,228), as applied to claims 1 and 38 above, and further in view of Betting et al., (6,513,345).**

Smith discloses all the limitations of claim 18 and 35 except the inlet channel, whereby inhalation air is drawn in through the inlet channel and whereby a swirling flow of the inhalation air is created between the inlet channel and the mouthpiece. Betting discloses a device that utilizes a convergent-divergent nozzle for separating inertia from a supersonic gas flow. The device has an inlet channel (16) and whereby a swirling flow or air (52) is created between the inlet and the outlet of the device.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the Laval nozzle (convergent-divergent nozzle) disclosed by Smith with the convergent-divergent nozzle taught by Betting because of the reasonable expectation of obtaining a dry powder inhaler with the capability of providing a more concentrated dose of powder to a user.

Regarding claims 19 & 36, Betting discloses a device wherein the gas flow (56) and the separated component (54) outlet (19) are directed in opposite directions.

Regarding claim 20, Betting discloses a Laval nozzle (convergent-divergent nozzle 20) and an inlet channel (16) arranged in such a way that the aerosol flow

leaving the Laval nozzle and the inhalation air collide with each other at an angle (caused by 60) when the air is swirled.

Regarding claims 21 & 37, Betting discloses a device characterized in that a channel that guides the aerosol flow (24) and the inlet channel (16) for the inhalation air empty into a swirl chamber (between 26 & 30), whereby the aerosol is directed from the swirl chamber to a divergent-convergent nozzle (at 30).

Regarding claim 41, Smith discloses all the limitations of claim 41 except the powder particles achieving a supersonic speed at an end of the narrowing inlet section of the Laval nozzle and are decelerated to subsonic speed in the widening outlet section. Smith discloses that the "gas source 20 will provide gas as at a relatively high pressure, usually being sufficient to provide for sonic flow past the outlet end 18." Betting teaches using supersonic gas flow to separate particles from a gas and that separation efficiency is significantly improved if the collection of the particles in the collecting zone takes place after a shock wave, i.e. in subsonic flow rather than in supersonic flow. See: col. 5, lines 34-60.

Regarding claim 42, Smith discloses a Laval nozzle with a narrowest cross section being about 100um to 1500 um.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ferris (3,698,390) which discloses a convergent-divergent nozzle medicament dispenser.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771